

REMARKS

Claims 1, 3 to 13, and 16 to 19 are pending in this application. No claim is currently allowed. Claims 1, 3 to 9, 13, and 16 to 19 stand rejected under 35 U.S.C. § 112, first paragraph. Claims 1, 3 to 5, 7 to 13, and 16 to 19 are newly rejected under 35 U.S.C. § 112, first paragraph. Claims 1, 3, 5, 7 to 13, and 16 to 19 stand rejected under 35 U.S.C. § 112, second paragraph. Claims 5, 13, and 16 to 19 are newly rejected under 35 U.S.C. § 112, second paragraph. Claims 1, 3 to 13, and 16 to 19 are rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1 to 16 of US-B-6,747,028. The specification is newly rejected for incorporation of essential material in the specification by reference. Applicants are herein amending claims 1, 5, 6, and 13.

Amendments to Claims

Applicants are herein amending claims 1, 5, 6, and 13:

- Applicants are amending claim 1 to delete “ester or amide prodrug” and to delete “isoquinolinyl” from R¹.
- Applicants are amending claim 5 to present it in more proper Markush format.
- Applicants are amending claim 6 to present it as an independent claim, to delete “ester or amide prodrug,” to add a missing bracket, and to add two additional species within the genus of Group I of Restriction Requirement. Support for the amendment may be found in the specification, *inter alia*, pages 74 and 75 (Compounds 98 and 114, respectively)
- Applicants are amending claim 13 to correct the chemical structures shown in formulae (X-a) and (I-a-1-3-1). Support for the amendment may be found in claim 13, as originally filed.

Applicants respectfully submit that no new matter is introduced by the amendments to the claims.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1, 3 to 9, 13, and 16 to 19 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for use of the phrase “ester or amide prodrug”. While applicants disagree that the phrase is not enabled, applicants are herein amending claims 1 and 6 to delete the phrase, thereby rendering moot the enablement rejection. Accordingly, applicants request withdrawal of the rejection of 1, 3 to 9, 13, and 16 to 19 stand rejected under 35 U.S.C. § 112, first paragraph.

Claims 1, 3 to 5, 7 to 13, and 16 to 19 are newly rejected under 35 U.S.C. § 112, first paragraph, as allegedly introducing new matter with the prior amendment to claim 1 to specify that R¹ could be “isoquinolinyl”. While applicants disagree that the amendment introduced new matter, applicants are herein amending claim 1 to delete the term, thereby rendering moot the written description rejection. Accordingly, applicants request withdrawal of the rejection of claims 1, 3 to 5, 7 to 13, and 16 to 19 stand rejected under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1, 3, 5, 7 to 13, and 16 to 19 stand rejected under 35 U.S.C. § 112, second paragraph because one of the moieties in monovalent R² is allegedly divalent. Contrary to the assertion in the latest Office Action, applicants wish to point out that they did, in fact, address the rejection in response to the previous Office Action (See page 19, last paragraph):

Applicants submit that the term “C₂₋₅alkanediyl” in the definition of R² is accurately presented as a divalent moiety. Please note that “C₂₋₅alkanediyl” is defined as an optional substituent on the C₁₋₁₀alkyl substituted with N(R⁶)₂. This implies that the divalent “C₂₋₅alkanediyl” is linked at both ends to the C₁₋₁₀alkyl chain. As such, R² remains monovalent, as required. Table 12 includes several examples, including compounds 157, 168, and 175, which exemplify the “C₂₋₅alkanediyl” on the C₁₋₁₀alkyl chain.

Accordingly, applicants request withdrawal of the rejection of claims 1, 3, 5, 7 to 13, and 16 to 19 under 35 U.S.C. § 112, second paragraph.

Claims 5, 13, and 16 to 19 are newly rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite with respect to the Markush language in claim 5 and the chemical structures for formulae (X-a) and (I-a-1-3-1) in claim 13. Applicants are herein amending claim 5 to use more appropriate Markush language and amending claim 13 to correct the chemical structures for formulae (X-a) and (I-a-1-3-1), thereby rendering moot the indefiniteness rejection. Accordingly, applicants request withdrawal of the rejection of claims 5, 13, and 16 to 19 stand rejected under 35 U.S.C. § 112, second paragraph.

Double Patenting Rejection

Claims 1, 3 to 13, and 16 to 19 are rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1 to 16 of US-B-6,747,028. Applicants traverse the rejection because claims 1, 3 to 13, and 16 to 19 are patentably distinct from claims 1 to 16 of US-B-6,747,028. Applicants submit that the claims 1 to 16 of US-B-6,747,028 are directed to compounds where R¹ represents a monocyclic heterocycle, whereas the present invention relates to compounds where R¹ represents a bicyclic heterocycle. Accordingly, applicants request withdrawal of the obviousness-type double patenting rejection.

Objection to Specification

The specification is objected to as allegedly improperly incorporating essential information in the specification by reference to a foreign application/patent or a publication. Applicants do not appear to have “incorporated by reference” any foreign application/patent or publication. Accordingly, applicants request withdrawal of the objection to the specification.

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PATENT

Conclusions

Applicants respectfully request:

- (1) entry of the amendments to the claims; and
- (2) reconsideration and withdrawal of the rejection of claims 1, 3 to 13 and 16 to 19;
- (3) reconsideration and withdrawal of the objection to the specification; and
- (4) allowance of claims 1, 3 to 13 and 16 to 19.

If the Examiner is of a contrary view, the Examiner is requested to contact the undersigned attorney at (215) 557-3861.

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